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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,195	04/22/2004	Marcia Buiser	01194-459001	7713

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/830,195	BUISER ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,11,23-31,49-53,60,62 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,11,23-31,49-53,60,62,63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/2009 has been entered.

Status of Claims

Claims 1 and 62 have been amended. Claims 5-10, 12-22, 32-48, 54-59 and 61 have been cancelled. Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are pending and are examined herein on the merits for patentability.

Response to Arguments

Any rejection not reiterated herein has been withdrawn as being overcome by amendment.

Applicant's arguments have been considered but are moot in view of new grounds for rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) and Greene (US 2002/0177855), in view of Lanphere *et al.* (US 2003/0185895).

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The device generally comprises a flexible elongated filament having a linear sequence of beads disposed thereon. The beads may be fixedly connected to the filament. The string of beads may be configured to the exact length needed. The beads may be porous (abstract). The embolic device is used to occlude blood flow and/or initiate blood clotting upon introduction to the body via a catheter (column 1, lines 14 – 25). The string of beads includes a filament (i.e. a link) and beads. The beads have diameters from 0.002 inches to 0.0018 inches, and may be

made of a variety of materials, including polymers, radioopaque polymers, metals. The beads may be integrally formed of the material of the filament (column 4, line 24). The string of beads may be comprised of beads of several different materials (column 4, lines 25 – 40). The filament can be a multi or monofilament polymer (column 5, line 21). The string of beads may be configured as a drug delivery device, wherein the beads are porous and contain a medicament for controlled release into the interior of the body (column 2, lines 44 – 47).

Greene discloses an embolization device for occluding a body cavity which includes one or more elongated hydrophilic embolizing elements non-releasably carried along the length of an elongated filamentous carrier (abstract). The embolizing agents (micropellets) may be made of a macroporous polymeric material or a porous, environmentally-sensitive, expansile hydrogel (abstract and paragraphs 0085 – 0088). The carrier (i.e. link) is preferably a nickel/titanium wire, but may also be formed from a polymer (paragraph 0093). The carrier has a diameter of approximately 0.04 mm (i.e. 0.0015 inches) (paragraph 0092). The length of the carrier is variable depending on the size of the vascular site to be embolized (paragraph 0085). See also Figure 1. The device may be contained in saline solution (paragraph 0029). The devices may be used to deliver therapeutic agents (paragraph 0141).

Jacobsen and Greene do not specifically recite that the porous beads have the pore size distribution as claimed.

Lanphere discloses a drug delivery device which is a substantially spherical polymer particle having an internal reservoir region including relatively large pores and a

metering region substantially surrounding the reservoir region having fewer relatively large pores (paragraph 0004). A sustained, controlled-dosage release of a therapeutic agent can be achieved using the particles (paragraph 0010). The particles have a diameter in the range of 1 cm or less, e.g., 5 mm to 1 mm or less, e.g., about 1200 microns or less, and about 10 microns or more, e.g. about 400 microns or more and the pores are about 50 or 35 to 0.01 micron. Preferably, the particles are classified in size ranges of about 500-700 microns, about 700-900 microns, or about 900-1200 microns. The particles have a mean diameter in approximately the middle of the range and variance of about 20% or less, e.g. 15% or 10% or less (paragraph 0025). The particles can be considered to include a center region, C, from the center of the particle to a radius of about r/3, a body region, B, from about r/3 to about 2 r/3 and a surface region, S, from 2r/3 to r. The regions can be characterized by the relative size of the pores and the number of pores of given sizes. In embodiments, the center region has a greater number of relatively large pores than the body region and the surface region. The large pores are in the range of about 20 micron or more, e.g. 30 micron or more, or in the range of about 20 to 35 micron. The body region has a greater number of intermediate size pores than the surface region. The intermediate size pores are in the range of about 5 to 18 micron. In embodiments, the regions may also have different densities, with the density of the surface region being greater than the density of the body region, and the density of the body region being greater than the density of

the center region. The size of the pores in each of the regions can also be characterized by a distribution. In embodiments, the predominant pore size(s) in the center region being greater than the predominant pore size(s) in the body region and the predominant pore size(s) in the body region is greater than the predominant pore size(s) in the surface region. In embodiments, in the predominant pore size in the center region is 20 micron or more, e.g. 30 microns or more, or in the range of about 20 to 35 microns. The predominant pore size in the body region is about 18 micron or less, e.g. about 15 micron or less, or in the range of about 18 to 2 micron. The pores in the surface region are preferably predominantly less than about 1 micron, e.g. about 0.1 to 0.01 micron (paragraph 0026-0027). The particles can be used in chemoembolization (paragraph 0066). The particles are suspended in a carrier fluid, which may include saline and a contrast solution (paragraph 0030). The particles are preferably PVA (paragraph 0021).

Lanphere fails to recite that at least two particles are connected.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the porous particles having a pore size distribution as disclosed by Lanphere as the porous beads in the embolic device comprised of a linear sequence of flexibly interconnected miniature beads, taught by Jacobsen, or the embolic micropellets positioned along the length of a carrier, taught by Greene, because the embolic devices of Jacobsen or Greene and the particles of Lanphere are used for controlled release drug delivery (see Jacobsen column 2, lines 44 – 47). One would have been motivated to do so because Lanphere specifically teaches that a polymeric

particle having an internal reservoir region including relatively large pores and a metering region having fewer relatively large pores controls the release of an agent from the particle, and are particularly useful for delivery of desired drug dosages for an extended period of time (see Lanphere paragraphs 0003 – 0010). It would have been further obvious to one of ordinary skill in the art at the time of the instant invention to apply the porous PVA particles taught by Lanphere in an interconnected form, as taught in the device of Jacobsen, because both the porous particles of Lanphere and the interconnected porous beads of Jacobsen are used for embolization. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Jacobsen specifically teaches that hydrophilic particles which are used for occluding blood flow tend to become dislodged from the target site and migrate within the body potentially causing trauma or unwanted thrombosis, and that providing a device comprising a linear sequence of interconnected miniature beads is superior to individual particles because the device is less susceptible to migration within the body (column 1 – 2). Regarding claims 3 and 4, Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges. Regarding the limitations of link aspect ratio, ratio, length, it is noted that Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges, which would be directly related to aspect ratio within the extremely broad ranges based on the diameter of the particles as a ratio to any length available. Greene and Jacobsen both teach that length

of chain/filament, etc. may be selected by the user. See also Figures of Jacobsen, for example such as Figure 4. The width of the length is approximately 0.1 cm, and the length shown is approximately 5.5 cm. Such a width/length ratio shown would be within the widely varying claimed range of aspect ratio, especially since Jacobsen teaches that any length may be selected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 7,131,997; 7,449,236; 7,462,366; 7,588,780 and 7,611,542 in view of Jacobsen *et al.* (US 6,530,934) and Greene (US 2002/0177855).

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Application Serial No. 12/235,978, 12/236,051 and 10/651,475 in view of Jacobsen *et al.* (US 6,530,934) and Greene (US 2002/0177855).

The claims of the 7,131,997; 7,449,236; 7,462,366; 7,588,780 and 7,611,542 patents and the 12/235,978, 12/236,051 and 10/651,475 applications are drawn to polymeric particles having the pore size distribution overlapping in scope with that which is now claimed. While the embolic/therapeutic particles of the 7,131,997; 7,449,236; 7,462,366; 7,588,780 and 7,611,542 patents and the 12/235,978, 12/236,051 and 10/651,475 applications do not specifically recite that the particles are present on a particle chain comprising at least two connected particles and a link that connects the at least two connected particles, it is well known in the art to provide porous particles on a chain for embolization, as shown by Jacobsen and Greene. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Jacobsen specifically teaches that hydrophilic particles which are used for occluding blood flow tend to become dislodged from the target site and migrate within the body potentially causing trauma or unwanted thrombosis, and that providing a device comprising a linear sequence of interconnected miniature beads is superior to individual particles because the device is less susceptible to migration within the body (column 1 – 2). Regarding chain length, Jacobsen and Greene teach that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges. Regarding link width,

Greene teaches the claimed width. Regarding the limitations of link aspect ratio, ratio, length, it is noted that Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges, which would be directly related to aspect ratio within the extremely broad ranges based on the diameter of the particles as a ratio to any length available. Greene and Jacobsen both teach that length of chain/filament, etc. may be selected by the user. See also Figures of Jacobsen, for example such as Figure 4. The width of the length is approximately 0.1 cm, and the length shown is approximately 5.5 cm. Such a width/length ratio shown would be within the widely varying claimed range of aspect ratio, especially since Jacobsen teaches that any length may be selected.

Accordingly, the claims are overlapping in scope and are obvious variants of one another.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is (571)272-9928. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday 9 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS